Proposed Registration Decision PRD2011-16

Boscalid Seed Treatment

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Overview

Proposed Registration Decision for BAS 516 F ST

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Boscalid Technical Fungicide and BAS 516 F ST, containing the active ingredients boscalid and pyraclostrobin as a seed treatment, to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

Boscalid was first issued temporary registration in Canada as a foliar fungicide in 2003 as Lance WDG Fungicide (Registration Number 27495) and Cadence WDG Fungicide (Registration Number 27496). A detailed review for the initial registrations can be found in Regulatory Note REG2004-02, *Boscalid/BAS 510*. The products were converted to full registration in 2009; a detailed review for the conversion can be found in Proposed Registration Decision PRD2008-04, *Boscalid*. The current registration decision addresses the major new use of boscalid as a seed treatment. A decision on the major new use of pyraclostrobin as a seed treatment is presented in Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Boscalid Technical Fungicide and BAS 516 F ST for canola and canola-quality *Brassica juncea* seed treatment.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on BAS 516 F ST, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on BAS 516 F ST, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is Boscalid?

Boscalid was first registered in 2003 in Lance WDG Fungicide as a foliar treatment for canola, legumes, and fruit and vegetable crops and in Cadence WDG Fungicide for turf use. Additional products have also been registered including Pristine WG Fungicide (Registration Number 27985), which is a combination product containing both pyraclostrobin and boscalid for use on various crops and ornamentals. Boscalid inhibits spore germination, germ tube elongation and sporulation. Although it has systemic and curative properties, boscalid is intended as a preventative fungicide.

Health Considerations

Can Approved Uses of Boscalid Affect Human Health?

Potential exposure to boscalid may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when boscalid products are used according to label directions.

In laboratory animals, boscalid exhibited low acute toxicity by the oral, dermal and inhalation routes of exposure; it was minimally irritating to the eyes and slightly irritating to the skin. Boscalid was not a skin allergen.

The end-use product, BAS 516 F ST, is of low toxicity in rats via the oral, dermal and inhalation routes. It is not irritating to the eyes, but is mildly irritating to the skin of rabbits. It is a skin allergen in guinea pigs.

There was no indication that boscalid caused damage to the nervous system and there were no effects on reproduction. There was no evidence that the young animal was more sensitive to boscalid toxicity than the adult animal. In repeat dose studies, the target organ of toxicity was the liver. Boscalid was not genotoxic (did not cause damage to DNA) in a battery of tests. Boscalid induced thyroid tumours in rats. Sufficient data were provided to determine a threshold for development of the tumours. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Occupation Risks From Handling BAS 516 F ST

Occupational risks from handling BAS 516 F ST are not of concern when label directions are followed.

Farmers and custom applicators have potential for exposure to pyraclostrobin and boscalid during mixing, loading and application as a seed treatment, and during bagging, loading and planting treated canola seed. The occupational exposure for these use scenarios is not of concern when the product is used according to the label directions.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most boscalid relative to body weight, are expected to be exposed to less than 19% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from boscalid is not of concern for all segments of the population. There is no evidence that boscalid is carcinogenic; therefore, a cancer dietary exposure assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of boscalid is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA)*. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

The MRLs for boscalid in/on canola and mustard (oilseed variety) have been established based on the data generated following foliar application use. The proposed seed treatment use of boscalid is not expected to result in residues exceeding their established MRLs.

Environmental Considerations

What Happens When Boscalid Is Introduced Into the Environment?

Environmental risks are not of concern when label directions are followed

Boscalid is introduced in the environment when it is used as a seed treatment in BAS 516 F ST. A limited exposure in soil and water is expected when boscalid is formulated as a seed treatment. However, birds and mammals may be exposed to this substance if they feed on treated seeds. A risk assessment has indicated that boscalid may cause adverse reproductive effects in birds if high numbers of seeds treated with BAS 516 F ST are ingested.

Value Considerations

What Is the Value of BAS 516 F ST?

BAS 516 F ST contains two active ingredients, pyraclostrobin and boscalid, that have broad range, complementary disease control spectra

Seed- and soil-borne pathogens cause diseases that manifest in reduced stands, poor seedling vigour and reduced yield and quality. Seed treatment fungicides increase the likelihood of producing healthy seedlings, which could contribute to improved yield.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of BAS 516 F ST to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading, calibrating, applying, bagging/stacking, cleaning/repairing treatment equipment and handling canola seed treated with BAS 516 F ST must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When planting treated seed, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When treating seed in commercial seed treatment facilities, closed transfer including closed mixing, loading, calibrating and closed treatment equipments must be used. Use of an open transfer system is allowed when treating seed on-farm only.

Environment

A precautionary label statement is included on the label to inform the user of the hazard to birds. Also, treated seeds that are spilled or exposed must be incorporated into the soil or cleaned-up from the soil surface.

Next Steps

Before making a final registration decision on BAS 516 F ST, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on BAS 516 F ST (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

BAS 516 F ST

This Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Boscalid Technical Fungicide and BAS 516 F ST for canola and canola-quality *Brassica juncea* seed treatment. This Science Evaluation addresses the major new use of boscalid as a seed treatment. For a detailed review of the major new use of pyraclostrobin as a seed treatment, please refer to Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Boscalid
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	2-chloro-*N*-(4′-chlorobiphenyl-2-yl)nicotinamide
2. Chemical Abstracts Service (CAS)	2-chloro-*N*-(4′-chloro[1,1′-biphenyl]-2-yl)-3-pyridinecarboxamide
CAS number	188425-85-6
Molecular formula	$C_{18}H_{12}Cl_2N_2O$
Molecular weight	343.21
Structural formula	
Purity of the active ingredient	99 % nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product— Boscalid Technical Fungicide

Property	Result
Colour and physical state	White powder
Odour	Faint smoky
Melting range	143.4–143.6 °C
Boiling point or range	Not applicable for a solid
Density	1.39 g/cm^3
Vapour pressure at 20°C	7 x 10^{-7} Pa
Henry's law constant at 20°C	9.73 × 10^{-10} atm·m^3/mol
Ultraviolet (UV)-visible spectrum	λ = 207 nm ε = 3.15 x 10^4 M^{-1} cm^{-1} λ = 228 nm ε = 1.98 x 10^4 M^{-1} cm^{-1} λ = 290 nm ε = 1.53 x 10^3 M^{-1} cm^{-1} λ = 300 nm ε = 5.31 x 10^2 M^{-1} cm^{-1}

Property	Result
	(no absorbance from above 300 to 400 nm)
Solubility in water at 20°C	4.64 mg/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — Solubility N,N-dimethylformamide — >25.0 dichloromethane — 20 - 25 acetone — 16 - 20 ethyl acetate — 6.7 – 8 acetonitrile — 4.0 – 5.0 methanol — 4.0 – 5.0 toluene — 2.0 – 2.5 n-heptane — < 1.0 1-octanol — <1.0 olive oil — <1.0 2-propanol — <1.0
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow}= 2.96
Dissociation constant (pK_a)	Does not dissociate under environmental conditions
Stability (temperature, metal)	Reacts very weakly with potassium permanganate. Does not react with iron, water or the fire extinguishing agent monoammonium phosphate (MAP). It is a very weak reducing agent. Stable to normal and elevated temperatures

End-use Product—BAS 516 F ST

Property	Result
Colour	White
Odour	Mild chemical
Physical state	Liquid
Formulation type	Suspension
Guarantee	Pyraclostrobin.....100 g/L Boscalid.....200 g/L
Container material and description	High density polyethylene (HDPE) jugs, drums or totes, 0.1 L to 1000 L
Density	1.116 g/mL
pH of 1% dispersion in water	6.2
Oxidizing or reducing action	The product does not react with iron, a reducing agent. It reacts weakly with oxidizing agents.
Storage stability	There was no change in active ingredient concentration after storage in commercial HDPE 1 L bottles for 2 years at 20°C.
Corrosion characteristics	The product demonstrated no corrosion to the HDPE packaging after storage for 2 years at 20°C.
Explodability	The product is not expected to be explosive.

1.3 Directions for Use

Crop	Target Disease	Product use rate in ml/100 kg seed (kg a.i./100 kg seed)
Canola and canola-quality *Brassica juncea*	Control of seed rot caused by *Fusarium* spp. and *Rhizoctonia solani*	100–200 (0.03–0.06)

For control of seed rot and seedling blight caused by *Pythium* spp. in canola, BAS 516 F ST may be mixed with the following products:

- Apron XL LS Fungicide
- Allegiance FL

For control of flea beetle in canola, BAS 516 F ST may be mixed with the following products:

- Vault 50 FS Insecticide Seed Treatment
- Poncho 600 FS Seed Treatment Insecticide

The user must read and follow all label guidelines (including precautions, limitations, rates and directions for use) for all mix partners.

1.4 Mode of Action

Refer to Regulatory Note REG2004-02, *Boscalid/BAS 510* and Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*.

2.0 Methods of Analysis

The methods provided for the analysis of the active ingredient and the impurities in Boscalid Technical Fungicide and of the active ingredients in BAS 516 F ST have been validated and assessed to be acceptable. The method for formulation analysis is acceptable for use as an enforcement analytical method.

Refer to Regulatory Note REG2004-02, *Boscalid/BAS 510* and Proposed Registration Decision PRD2009-08, *Boscalid*, for a detailed assessment of the methods for residue analysis.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Regulatory Note REG2004-02, *Boscalid/BAS 510* and Proposed Registration Decision PRD2008-04, *Boscalid* for details on technical boscalid.

The end-use product, BAS 516 F ST, is of low acute toxicity in rats via the oral (LD_{50} > 2000 mg/kg), dermal (LD_{50}> 5000 mg/kg bw), and inhalation (LD_{50}> 2.58 mg/L) routes (Appendix I, Table 1). It is not irritating to the eyes, but is mildly irritating to the skin of rabbits. It is a dermal sensitizer in guinea pigs using the Buehler method.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for boscalid. The database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the 2-generation reproductive toxicity study. Parents and offspring demonstrated similar toxicological effects. The effects were observed at the highest dose tested. In the developmental toxicity rat study, no adverse toxicological effects were observed. In the rabbit developmental toxicity study, increased abortions were noted at the highest dose tested. No other adverse toxicological effects were observed. Consequently the 10-fold factor required under the *Pest Control Products Act* was reduced to 1-fold.

3.2 Determination of Acute Reference Dose and Acceptable Daily Intake

Refer to Regulatory Note REG2004-02, *Boscalid/BAS 510* and Proposed Registration Decision PRD2009-08, *Boscalid*.

3.3 Occupational and Residential Risk Assessment

3.3.1 Toxicological Endpoints

Occupational exposure to BAS 516 F ST is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes.

Risk assessments for occupational exposure were based on the following boscalid endpoints:

- Short- to intermediate-term endpoint (dermal and inhalation) - based on a NOAEL of 14 mg/kg bw/day from the rat developmental neurotoxicity study with an MOE of 100.

For pyraclostrobin endpoints, please refer to please refer to Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*.

3.3.1.1 Dermal Absorption

A rat *in vivo* dermal absorption study was previously reviewed by the Agency for boscalid and a dermal absorption value of 15% was chosen as the most appropriate for occupational exposure. Please refer to Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment* for the dermal absorption value for pyraclostrobin.

3.3.2 Occupational Exposure and Risk

Workers that mix, load and apply a seed treatment product commercially could be exposed for up to two months of the year (intermediate-term duration) and those that treat on-farm could be exposed for only a few days (short-term duration). For workers that plant treated seed, exposure is expected to be short-term in duration, since planting can only happen over a period of less than a month.

3.3.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

A dust-off study, designed to measure the potential dusting off of various seeds treated with different end-use products, showed that wheat has a higher dust potential than either barley or corn. Therefore, extrapolating seed treatment exposure data from wheat seed treatment studies to either barley or corn should not underestimate exposure.

Two surrogate passive dosimetry studies were used to estimate exposure to pyraclostrobin and boscalid.

In the first surrogate study, the exposure of agricultural workers to both fluquinconazole and prochloraz was measured during the commercial treating of wheat seed. Thirty-nine trials were conducted with commercial seed treating and bagging equipment. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under a single layer of clean clothing during treating, bagging and calibrating, with the addition of Tyvek coveralls during cleaning of treatment equipment. Workers wore normal work clothing and gloves and some wore a hat and glasses. Inhalation exposure for each worker was measured by means of a personal air sampling pump.

Overall, the study was well conducted with no major limitations and confidence in the data is high. Measured residues were corrected for field recoveries $\leq$95%. Exposure estimates were based on the arithmetic mean and were normalized for the amount of active ingredient handled (except for cleaners where the total exposure was used). Inhalation values were adjusted for either a light breathing rate during mixing/loading/calibrating (16.7 L/min) or for a moderate breathing rate while bagging and cleaning (26.7 L/min).

Dermal exposure to fluquinconazole while bagging estimated to be 8.329 µg/kg a.i. handled (±11.98 µg/kg a.i.) without gloves and 7.54 µg/kg a.i. handled (±3.76 µg/kg a.i.) while wearing gloves. Inhalation exposure was estimated to be 0.78 µg/kg a.i. handled (±1.5 µg/kg a.i.). Total dermal exposure to fluquinconazole (while cleaning commercial seed treatment equipment) was estimated to be 169.81 µg/day (±297.79 µg/day) while wearing Tyvek coveralls over normal work clothing and gloves. Inhalation exposure was estimated to be 15.66 µg/day (±20.44 µg/day). Dermal exposure to fluquinconazole while mixing/loading and calibrating was estimated to be 0.29 µg/kg a.i. handled (±0.38 µg/kg a.i.) while wearing a single layer of clothing. Inhalation exposure was estimated to be 0.0049 µg/kg a.i. handled (±0.0074 µg/kg a.i.).

Dermal exposure to prochloraz while bagging estimated to be 11.717 µg/kg a.i. handled (±15.88 µg/kg a.i.) without gloves and 17.67 µg/kg a.i. handled (±18.16 µg/kg a.i.) while wearing gloves. Inhalation exposure was estimated to be 0.89 µg/kg a.i. handled (±1.65 µg/kg a.i.). Total dermal exposure to prochloraz while cleaning commercial seed treatment equipment, was estimated to be 240.36 µg/day (±542.63 µg/day) while wearing Tyvek coveralls over normal work clothing and gloves. Inhalation exposure was estimated to be 71.46 µg/day (±12.62 µg/day). Dermal exposure to prochloraz while mixing/loading and calibrating was estimated to be 0.88 µg/kg a.i. handled (±0.84 µg/kg a.i.) while wearing a single layer of clothing. Inhalation exposure was estimated to be 0.016 µg/kg a.i. handled (±0.035 µg/kg a.i.). For risk assessment purposes, the highest exposure value of the two actives was chosen since it should not underestimate exposure.

In the second surrogate study, the exposure of farmers to anthraquinone, fludioxonil and/or imidacloprid was measured during the treatment and planting of wheat grain seed. Twelve trials were conducted with portable treating equipment on-farm. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under a single layer of clean clothing. Workers wore normal work clothing and most wore gloves, a hat and glasses. Some workers also wore a cotton apron. Inhalation exposure for each worker was measured by means of a personal air sampling pump.

This study had some major limitations: low field recoveries of anthraquinone and fludioxonil for filters and inner dosimeters, field fortification samples that were not analyzed concurrently with field samples, and small sample sizes for each activity and active ingredient. As such, the 90th percentile unit exposure values from this study are recommended to be used for risk assessment purposes.

Twelve replicates were involved with mixing/loading and ten replicates were not involved with mixing/loading. Eleven replicates were monitored for exposure to anthraquinone, which had dermal and inhalation unit exposures of 164.3 µg/kg a.i. handled and 7.865 µg/kg a.i. handled, respectively. Seven replicates were monitored for exposure to fludioxonil, which had dermal and inhalation unit exposures of 126.6 µg/kg a.i. handled and 6.401 µg/kg a.i. handled, respectively. The dermal and inhalation unit exposures were 101.3 µg/kg a.i. handled and 13.65 µg/kg a.i. handled for the four replicates that were monitored for imidacloprid exposure. With all the replicates pooled together, the 90th percentile dermal exposure was 141.9 µg/kg a.i. handled and the 90th percentile inhalation exposure was 7.825 µg/kg a.i. handled.

The PMRA assumes that worker activities and numbers of people involved vary at different commercial seed treatment facilities depending on the size of the operation and degree of automation. Usually one worker prepares the treatment slurry (mixer/loader), which involves open transfer of the product into the premix tank for smaller containers, and closed transfer for bulk containers. Another worker (often the mixer/loader) oversees the seed treatment area (treater/coater). One or more workers are involved in bagging the seeds as well as sewing, tagging and stacking seed bags. Most seed treatment plant workers have eight-hour shifts and workers may rotate duties to other areas.

The worker exposure studies monitored only a single individual who per task (mixing/loading/calibrating/cleaning/bagging and stacking). This should not underestimate exposure since larger facilities will rotate worker positions throughout the day and tend to use closed mixing and loading equipment. The exposure values from a commercial treater studies were used to estimate exposure while treating.

Exposure and risk estimates are required for a farmer performing all tasks, including mixing, loading, calibrating, treating and planting, for a short term duration of exposure (i.e., up to 30 days). The exposure values from the on-farm treater study were used to estimate exposure while treating.

Systemic exposure (mg/kg bw/day) =

$$\frac{\text{systemic unit exposure} \times \text{fraction absorbed} \times \text{application rate} \times \text{kg seeds treated/d} \times \text{conversion factor}}{\text{body weight}}$$

A dermal absorption value of 23% was used for estimating systemic exposure to pyraclostrobin and 15% was used for estimating exposure to boscalid. Absorption from inhalation was considered to be 100%.

Depending on the size of the commercial seed treatment facility and the type of seed treating equipment, canola seed treatment capacity varies from 1,850 kg up to 75,000 kg seed per day. To estimate exposure the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates at commercial seed treatment facilities:

The amount canola seed treated/day = 75,000 kg
Body weight = 70 kg

Depending on the size of the on-farm seed treatment facility and the type of seed treating equipment, canola seed treatment capacity varies up to 600 kg seed per day. To estimate exposure the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates during on-farm seed treatment:

The amount canola seed treated/day = 600 kg
Body weight = 70 kg

Margins of exposure (MOEs) for short and intermediate durations of exposure for commercial and on-farm treatment of seeds ranged from 225 to 2,041,667 and are considered to be acceptable.

3.3.2.2 Exposure and Risk Assessment for Workers Planting Treated Seed.

A passive dosimetry study was previously submitted to the Agency. The study measured exposure to triadimenol of workers planting treated cereal seed. This study was considered appropriate for estimating exposure to farmers and commercial workers during planting of canola seed treated with pyraclostrobin and boscalid.

Systemic exposure (mg/kg bw/d) =

$$\frac{\text{unit exposure} \times \text{amount handled a.i. per day x fraction absorbed}}{\text{body weight}}$$

A dermal absorption value of 23% was used for estimating systemic exposure to pyraclostrobin and 15% was used for estimating exposure to boscalid. Absorption from inhalation was considered to be 100%.

Depending on the size of the seed planting equipment and the seeding rate, canola seed planting capacity varies from 288 kg up to 1000 kg seed per day for farmers and commercial planters. To estimate exposure the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates at commercial seed treatment facilities:

The amount canola seed planted/day (commercial) = 1,000 kg
The amount canola seed planted/day (on-farm) = 600 kg
Body weight = 70 kg

Acceptable margins of exposure were obtained for commercial and on-farm planters that use open cab planters.

Since farmers will treat and plant their own seed (all on one day), a combined mixer/loader/ treater/planter exposure assessment is required. The total exposure values from on-farm treating (Appendix I, Table 3) were combined with the planting exposure (Appendix I, Table 7) values above to provide an estimate of exposure to workers who treat on-farm and then plant the seeds they treated.

Acceptable margins of exposure were obtained for farmers that mix/load/treat and plant canola seed treated with pyraclostrobin and boscalid using an open cab planter.

3.3.3 Residential Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal when planting treated seed.

3.4 Food Residues Exposure Assessment

3.4.1 Residues in Plant and Animal Foodstuffs

Boscalid is currently registered for foliar application on various crops including canola and canola-quality *Brassica juncea* (mustard, oilseed variety). Refer to Regulatory Note REG2004-02, *Boscalid/BAS 510* and Proposed Registration Decision PRD2009-08, *Boscalid* for the residue definition for risk and enforcement purposes, the field trial data on various crops resulting from foliar application, and the frozen storage stability of boscalid in plant and animal foodstuffs.

Based on foliar application, maximum residue limits (MRLs) for boscalid were established at 3.5 ppm for canola and mustard (oilseed variety), and at 5 ppm for canola oil and mustard seed oil. The seed treatment use of bocalid on canola and mustard (oilseed variety) at lower rate and longer pre-harvest intervals (PHIs) is not expected to result in residues exceeding the established MRL levels.

3.4.2 Dietary Risk Assessment

A refined chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™ Version 2.03). Aggregate exposure to boscalid from all supported food uses and water is considered acceptable. The highest aggregate exposure and risk estimate is for children 1 to 2 years old at 18.5% (0.02595 mg/kg bw/day) of the acceptable daily intake.

3.4.3 Aggregate Exposure and Risk

The aggregate risk for boscalid consists of exposure from food and drinking water sources only; there are no residential uses.

3.4.4 Maximum Residue Limits

No revision to the existing MRLs for boscalid is required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The physical and chemical properties and environmental fate of boscalid have been previously reviewed and are reported in Regulatory Note REG2004-02, *Boscalid/BAS 510*.

When boscalid is used as a seed treatment, a limited amount of this active ingredient is expected to reach non-target organisms that are found in soil and in water. However, birds and mammals may be exposed to boscalid if they feed on treated seeds.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. For seed treatments, the estimated environmental exposure concentrations (EECs) are based on the concentrations of pesticide in food (in this case, the seed) and the amount of food which is ingested. Ecotoxicology information includes acute and chronic toxicity data for birds and mammals. Acute toxicity endpoints are adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, assumed that unlimited treated seed are available for consumption and that 100% of the diet consists of treated seed) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios and might consider different toxicity endpoints. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

The effects of boscalid on terrestrial organisms from foliar treatment have been previously reviewed and are presented in Regulatory Note REG2004-02, *Boscalid/BAS 510*.

A new risk assessment was conducted to characterize the risk to birds and mammals that may feed on treated seed. This assessment was based upon previously reviewed information on the toxicity of boscalid to the following organisms (Appendix I, Table 9):

- 1 mammal species (acute oral and long term (reproduction) dietary exposure)
- 2 bird species (acute oral exposure, short- and long term (reproduction) dietary exposure)

The screening level risk quotients calculated for the boscalid component of the BAS 516 F ST formulation (Appendix I, Table 10) exceed the level of concern for small size birds on a dietary basis and all sizes of birds on a reproductive basis. The level of concern is not exceeded for mammals.

The avian acute dietary risk from the boscalid seed treatment use is considered to be negligible. This is supported by the fact that the LC_{50} values from the avian dietary studies were greater than the highest concentration tested, indicating that boscalid is practically non toxic to birds on a dietary basis. Given (i) that no effects were observed in the laboratory dietary study, (ii) that the dietary risk quotient only slightly exceeds the level of concern, and (iii) the conservative exposure scenario used for the assessment (assumed that 100% of the diet is comprised of treated seed), a risk from an acute dietary exposure to boscalid is not expected.

Screening level risk quotients for reproduction were higher than those for the acute assessment, reaching 6.2 and 4.8 for small and medium sized birds, respectively. These risk quotients were calculated based on the NOEL from a reproduction study with the bobwhite quail. The NOEL represents the dose at which no effects were observed during the study and is used as a starting point for the screening level assessment due to its conservative nature. For the current assessment, risk quotients were also calculated with the LOEL from the same bobwhite study in order to further explore the likelihood that adverse effects would occur in a field situation. Adverse effects observed at the LOEL under laboratory conditions included a statistically significant decrease in the number of eggs laid per hen, number of viable embryos, eggshell thickness, hatch rate of viable 18-day embryos, and number of 14-day old survivors. Risk quotients based on the LOEL exceeded the level of concern for small and medium sizes of birds, but not for large birds (Appendix I, Table 11). Because the level of concern was exceeded for smaller sizes of birds when using an endpoint at which effects were observed under laboratory conditions, it is possible that adverse reproduction effects would occur in the field.

However, it is important to note that all risk quotients were calculated based on a scenario in which an unlimited quantity of treated seed would be available for consumption and that 100% of the diet would consist of treated seed. When considering parameters such as availability of the seed and feeding preferences, the likelihood of adverse reproductive effects occurring in birds is much reduced. For example, not all seeds are available for consumption following planting (i.e., still covered by soil). Assuming that approximately 3% of the seeds would be available for consumption following planting, it was calculated that birds would need to feed on all treated canola seeds within a feeding area of 31 and 156 m^2 to reach the NOEL (104 and 519 m^2 to reach the LOEL) for small and medium sized birds, respectively. It is very unlikely that birds would eat all the seeds in such a large area. This is particularly true when considering feeding

preference, as canola seeds may not be the preferred choice for birds due to their bitter taste. Additionally, it can be argued that a large number of seeds must be consumed to reach the NOEL (275 and 1375 seeds for small and medium birds) and a very large number of seeds must be consumed to reach the LOEL (more than 900 for small birds and more than 4500 for medium size birds); to consume such a large amount of seeds is unlikely to occur under most conditions. Therefore, overall, the likelihood that exposure to boscalid from the ingestion of treated seeds on the field would be sufficient to cause adverse reproductive effects is low. Nonetheless, reproductive risk cannot be ruled out in the case of a seed spill, a scenario where a high amount of treated seeds would be readily available in a small area. Birds are known to exhibit an opportunistic feeding behaviour when a food source is readily available in large quantities. Given the magnitude of the reproductive effects observed from boscalid exposure under laboratory conditions, treated seeds that are spilled or exposed must be incorporated into the soil or cleaned-up from the soil surface in order to mitigate the potential risk to birds.
For an assessment of the pyraclostrobin component of BAS 516 F ST, please refer to Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*.

4.2.2 Risks to Aquatic Organisms

The effects of boscalid on aquatic organisms from spray applications have been previously reviewed and are presented in Regulatory Note REG2004-02, *Boscalid/BAS 510*.

A full assessment of aquatic risks was not conducted for the seed treatment use. Limited exposure to aquatic organisms is expected to result from the use of boscalid as a seed treatment given that the seeds are incorporated in the soil and also because the rate for the boscalid seed treatment use is substantially lower than for spray applications of this compound.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

A total of six trials on canola were submitted to support the claim for control of *Fusarium* spp. on canola. One trial could not be reviewed since the first plant count assessment was made 30 days after planting, which is too long to assess for the seed rot stage of seedling disease development. Based on the efficacy data submitted, the claim that BAS 516 F ST, when applied at 30 g ai/100 kg seed (10 g pyraclostrobin + 20 g boscalid), will control seed rot caused by *Fusarium* spp. is supported. The claim that BAS 516 F ST can be applied at the higher rate of 60 g ai/100 kg seed, under conditions of high disease pressure, is also supported. In the proposed use, the claim for control of *Fusarium* is extended to *Fusarium* species. In all *Fusarium* trials reviewed, two species were inoculated in a mixture: *F. avenaceum* and *F. solani*. Both *F. avenaceum* and *F. solani* has been found to cause disease symptoms in canola. This *Fusarium* spp. claim can be supported since the disease progression is similar for all Fusarium species that attack canola and evidence for *Fusarium* control was provided for two infecting *Fusarium* species.

Four trials on canola were provided to support the claim for control of *R. solani*. Based on the efficacy data submitted, the claim that BAS 516 F ST, when applied at 30 g ai/100 kg seed (10 g pyraclostrobin + 20 g boscalid), will suppress (not control) seed rot caused by *R. solani*, is supported. The claim that BAS 516 F ST is required at the higher rate of 60 g ai/100 kg seed is supported based on *Fusarium* efficacy requirements. Due to the nature of seed treatments, where only one application per season can be made, and the seeds are treated before the disease pressures can be assessed for the field, supporting the 30 – 60 g ai /100 kg seed rate for control of *Fusarium* spp. and *R. solani* is acceptable, especially if there is a history of high disease pressures in the field where the seeds will be planted.

The use on canola-quality *Brassica juncea* (oriental mustard) is supported based on extrapolation from results of canola trials. These two crops are closely related and crop production practices are the same. In addition, both crops are susceptible to *Fusarium* spp. and *Rhizoctonia solani* and disease development is identical.

Tank mixes with fungicides (Apron XL LS Fungicide or Allegiance FL) for the control of seed rot and seedling blight caused by *Pythium* spp. and insecticides (Vault 50 FS Insecticide Seed Treatment and Poncho 600 FS Seed Treatment Insecticide) for the control of flea beetle are proposed. Fungicide and insecticide efficacy trials demonstrated compatibility between BAS 516 F ST and the proposed fungicides and insecticides; namely Apron XL LS Fungicide, Allegiance FL, Vault 50 FS Insecticide Seed Treatment and Poncho 600 FS Seed Treatment Insecticide. Data was presented in one *Rhizoctonia* trial and three *Fusarium* trials, where BAS 516 F ST was applied with Allegiance FL (metalaxyl) and Vault 50 FS Insecticide Seed Treatment. In addition, three efficacy trials were submitted to test the efficacy of BAS 516 F ST in mixtures with Allegiance FL and Poncho 600 FS Seed Treatment Insecticide to control *Pythium* spp and flea beetles. No physical incompatibilities, adverse effects on fungicide efficacy and phytotoxicity were observed in any of the trials. The tank mix claims are supported.

5.2 Economics

Canola is an economically important crop in Canada. Canola prices increased in 2007 in response to consumer demand for canola oil and the prospect of producing bio-fuels. As a result, the cost of yield losses is also greater. The use of seed treatments mitigates losses from seedling diseases by improving germination, increasing plant emergence and fostering the production of healthier plants leading to increased yield.

5.3 Sustainability

5.3.1 Survey of Alternatives

Other seed treatments registered for control or suppression of the proposed diseases on canola and oriental mustard can be found in Appendix I, Table 12.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

The use of seed treatments results in less impact on non-target organisms, no spray drift, and reduced land surface exposure to pesticides. Common cultural practices include crop rotation to break the life-cycle of the pathogen and tillage to bury infected plant residues to prevent sporulation. However, crop rotation is less effective with pathogens with a broad host range (for example, *R. solani*) and no-till or reduced tillage is more common in prairie provinces because it conserves moisture, controls weeds and the economic savings outweigh the benefits to disease control incurred by tillage. As such, growers tend to rely on fungicides to manage disease.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

BAS 516 F ST contains a group 11 (strobilurin) fungicide and a group 7 (succinate dehydrogenase inhibitor (SDHI)). Strobilurin and SDHI resistance in fungal populations has been developing; however, the risk of fungicide resistance is believed to be very low with seed treatment products. To maintain the performance of BAS 516 F ST and other strobilurin or SDHI fungicides, appropriate resistance management strategies should be implemented. Follow the label instructions and rotate with fungicides having a different mode of action. Monitor fungal populations for resistance development.

5.3.4 Contribution to Risk Reduction and Sustainability

Seed treatments offer effective control against seed- and soil-borne pathogens at low application rates. The fungicide is only applied once, reducing the risk of development of pest resistance that may result from repeated applications.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, the active ingredients in BAS 516 F ST and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- It was previously determined that technical grade boscalid does not meet all Track 1 criteria and does not form any transformation products which meet Track 1 criteria (refer to Proposed Registration Decision PRD2009-08, *Boscalid* for the most recent TSMP assessment).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade boscalid as well as the BAS 516 F ST end-use product do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[9]

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

8 DIR2006-02, PMRA Formulants Policy.

9 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

Refer to Proposed Registration Decision PRD2009-08, *Boscalid* for a summary of the toxicology of boscalid.

Mixers, loaders and applicators handling BAS 516 F ST and workers planting treated seed are not expected to be exposed to levels that will result in an unacceptable risk when used according to label directions. The personal protective equipment on the product labels is adequate to protect workers.

The proposed seed treatment uses of boscalid do not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

7.2 Environmental Risk

Boscalid may cause adverse reproductive effects in birds when seeds treated with BAS 516 F ST are ingested. Treated seeds that are spilled or exposed must be incorporated into the soil or cleaned-up from the soil surface.

7.3 Value

Claims of control or suppression of seed rot caused *Rhizoctonia solani* and *Fusarium* spp. on canola and canola-quality *Brassica juncea* at the proposed rates are acceptable based on the submitted efficacy data.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Boscalid Technical Fungicide and BAS 516 F ST, containing the technical grade active ingredients boscalid and pyraclostrobin as a seed treatment, to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

The current registration decision addresses the major new use of boscalid as a seed treatment. A decision on the major new use of pyraclostrobin as a seed treatment is presented in Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*.

List of Abbreviations

µg	microgram(s)
a.i.	active ingredient
atm	atmosphere
bw	body weight
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
DNA	deoxyribonucleic acid
dw	dry weight
EEC	estimated environmental exposure concentration
FIR	food ingestion rate
g	gram(s)
HDPE	high-density polyethylene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
MAS	maximum average score
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
PCPA	*Pest Control Product Act*
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
ppm	parts per million
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of BAS 516 F ST Containing Boscalid

Study Type/Animal	Study Results	Reference
Acute oral toxicity/ Wistar rats	LD_{50} > 2000 mg/kg bw Low toxicity	1586111
Acute dermal toxicity/ Sprague-Dawley rats	LD_{50} > 5000 mg/kg bw Low toxicity	1586112
Acute inhalation toxicity (nose-only)/ Wistar rats	LC_{50} > 2.58 mg/L Low toxicity	1586113
Dermal irritation/ NZW rabbits	MAS[a] = 1.67/8 Mildly irritating	1586115
Eye irritation/ NZW rabbits	MAS[a] = 0/110 Non-irritating	1586114
Dermal sensitization (Beuhler test)/ Hartley guinea pigs	Sensitizer	1586116

[a] 24, 48 and 72 hours

Note: Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons.

Table 2 Unit Exposure Values Used for Commercial and On-Farm Mixer/Loader/Calibrator/ Baggers

Crop	Unit Exposure Values (µg/kg a.i. handled)	
	Dermal	Inhalation
Commercial Mixer/Loader/Calibrator [A]		
Canola	0.88	0.016
Commercial Bagging [B]		
Canola	17.67	0.89
On-Farm Mixing/loading/Bagging/Cleaning/Treating [C]		
Canola	141.9	7.825

[A] All values are from the commercial wheat study. Workers wore cotton jacket and trousers and gloves.
[B] All values are from the commercial wheat study. Workers wore a cotton jacket and trousers. Some workers also wore gloves.
[C] All values are from the on-farm cereal study. Workers wore a single layer. Most wore gloves. Some wore additional PPE; cotton apron, cap, mask and or spectacles.

Table 3 Exposure Estimates during Commercial and On-farm Mixing/Loading/Calibrating/ Bagging/Treating

Seed type	Max seed treated per day (kg)	Application rate (g a.i./ 100 kg seed)	Amount of a.i. handled per day (kg a.i./day) [A]	Dermal exposure (µg/kg bw/day)[B]	Dermal absorbed dose (µg/kg bw/day)[C]	Inhalation exposure (µg/kg bw/day)[D]	Dermal MOE [E]	Inhalation MOE [F]	Combined MOE [G]
Commercial Mixing/Loading/Calibrating									
Pyraclostrobin									
Canola	75,000	20	15	0.189	0.043	0.003	115,283	67,083	N/A
Boscalid									
Canola	75,000	40	30	0.377	0.057	0.007	247,475	2,041,667	220,721

Seed type	Max seed treated per day (kg)	Application rate (g a.i./ 100 kg seed)	Amount of a.i. handled per day (kg a.i./day) [A]	Dermal exposure (µg/kg bw/day) [B]	Dermal absorbed dose (µg/kg bw/day) [C]	Inhalation exposure (µg/kg bw/day) [D]	Dermal MOE [E]	Inhalation MOE [F]	Combined MOE [G]
Commercial Bagging									
Pyraclostrobin									
Canola	75,000	20	15	3.786	0.871	0.191	5,741	1,206	N/A
Boscalid									
Canola	75,000	40	30	7.573	1.136	0.381	12,325	36,704	9,227
On-Farm Mixing/Loading/Bagging/Cleaning/Treating									
Pyraclostrobin									
Canola	600	20	0.12	0.243	0.056	0.013	89,367	17,146	N/A
Boscalid									
Canola	600	40	0.24	0.487	0.073	0.027	191,841	521,832	140,273

[A] Amount of a.i. handled was calculated by multiplying the max amount of seed that could be treated per day by the application rate.
[B] Dermal exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the dermal unit exposure (Table 1) and dividing by the body weight (70 kg).
[C] Dermal absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23% pyraclostrobin, 15% boscalid)
[D] Inhalation exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the inhalation unit exposure (Table 1) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d for pyraclostrobin, target MOE = 300; 14 mg/kg bw/d for boscalid, the target MOE = 100)by the absorbed dermal exposure value
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/day for pyraclostrobin, 14 mg/kg bw/d for boscalid, the target MOE = 100)by the inhalation exposure value
[G] Combined MOE was calculated by dividing the NOAEL by the addition of the absorbed dermal exposure and the inhalation exposure values (applies to boscalid only since the dermal and inhalation NOAEL are the same), the target MOE is 100.

Table 4 Total Daily Exposure Values Used for Commercial Cleaning Exposure Assessment

Crop	Unit Exposure Values (µg a.i./day) [A]	
	Dermal	Inhalation
Canola	240.02	71.46

[A] All values are from the commercial wheat study. Workers wore a cotton jacket and trousers.

Table 5 Exposure Estimates during Commercial Cleaning

Seed type	Max seed treated per day (kg)	Application rate (g a.i./ 100 kg seed)	Total amount of dermal a.i. per day (µg a.i./d) [A]	Total amount of inhalation ai per day (µg a.i./d)	Dermal exposure (µg/kg bw/d) [B]	Dermal absorbed dose (µg/kg bw/d) [C]	Inhalation exposure (µg/kg bw/d) [D]	Dermal MOE [E]	Inhalation MOE [F]	Combined MOE [G]
Pyraclostrobin										
Canola	75,000	20	240.02	71.46	3.429	0.789	1.021	6340	225	N/A
Boscalid										
Canola	75,000	40	240.02	71.46	3.429	0.514	1.021	27,220	13,714	9,119

[A] Not normalized for the total amount of a.i. handled per day.
[B] Dermal exposure was calculated by taking the total amount of dermal exposure per day (Table 3) and dividing by the body weight (70 kg).
[C] Dermal Absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23% pyraclostrobin, 15% boscalid)

[D] Inhalation exposure was calculated by taking the total amount of inhalation exposure per day (Table 3) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d for pyraclostrobin, target MOE = 300; 14 mg/kg bw/d for boscalid, the target MOE = 100) by the absorbed dermal exposure value
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d for pyraclostrobin, 14 mg/kg bw/d for boscalid; target MOE = 100) by the inhalation exposure value
[G] Combined MOE was calculated by dividing the NOAEL by the addition of the absorbed dermal exposure and the inhalation exposure values (applies to boscalid only since the dermal and inhalation NOAEL are the same).

Table 6 Unit Exposure Values Used for Commercial Planting Exposure

Crop	Unit Exposure Values (µg/kg a.i. handled) [A]	
	Dermal	Inhalation
Canola	12580	250

[A] All values are from the cereal planting study (workers wore a single layer plus gloves and used open cab planters).

Table 7 Exposure Estimates during Commercial Planting of Treated Seed

Seed type	Max Seed planted per day (kg)	Application rate (g a.i./ 100 kg seed)	Amount of ai handled per day (g a.i./ day) [A]	Dermal exposure (µg/kg bw/day) [B]	Absorbed dose (µg/kg bw/day) [C]	Inhalation exposure (µg/kg bw/day) [D]	Dermal MOE [E]	Inhalation MOE [F]	Combined MOE [G]
Pyraclostrobin									
Canola	1000*	20	200	35.94	8.27	0.714	605	322	N/A
	600**		120	21.57	4.96	0.43	1,008	537	N/A
Boscalid									
Canola	1000*	40	400	71.89	10.78	1.43	1,298	9,800	1,146
	600**		240	43.13	6.47	0.86	2,164	16,333	1,911

[A] Amount of a.i. handled was calculated by multiplying the max amount of seed that could be treated per day by the application rate.
[B] Dermal exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the dermal unit exposure (Table 5) and dividing by the body weight (70 kg).
[C] Dermal absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23% pyraclostrobin, 15% boscalid)
[D] Inhalation exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the inhalation unit exposure (Table 5) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d for pyraclostrobin, target MOE = 300; 14 mg/kg bw/d for boscalid, the target MOE = 100) by the absorbed dermal exposure value
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d for pyraclostrobin, 14 mg/kg bw/d for boscalid) by the inhalation exposure value, the target MOE is 100.
[G] Combined MOE was calculated by dividing the NOAEL by the addition of the absorbed dermal exposure and the inhalation exposure values (applies to boscalid only since the dermal and inhalation NOAEL are the same), the target MOE is 100.
* Typical amount planted per day (commercial).
** Typical amount planted per day (on-farm).

Table 8 Exposure Estimates during On-Farm Treating and Planting of Treated Seed

Seed type	Max seed planted per day (kg)	Treating exposure (Dermal absorbed)	Treating exposure (Inhalation) (µg/kg bw/day)	Planting exposure (Dermal absorbed) (µg/kg bw/day)	Planting exposure (Inhalation) (µg/kg bw/day)	Combined dermal exposure (µg/kg bw/day)	Combined inhalation exposure (µg/kg bw/day)	Dermal MOE [A]	Inhalation MOE [B]	Combined MOE [C]
Pyraclostrobin										
Canola	600	0.056	0.013	4.96	0.43	5.016	0.442	997	520	N/A
Boscalid										
Canola	600	0.073	0.027	6.47	0.86	6.543	0.884	2,140	15,838	1,885

[A] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d for pyraclostrobin, target MOE = 300; 14 mg/kg bw/d for boscalid, the target MOE = 100) by the absorbed dermal exposure value

[B] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d for pyraclostrobin, 14 mg/kg bw/d for boscalid) by the inhalation exposure value, the target MOE is 100

[C] Combined MOE was calculated by dividing the NOAEL by the addition of the absorbed dermal exposure and the inhalation exposure values (applies to boscalid only since the dermal and inhalation NOAEL are the same), the target MOE is 100

Table 9 Toxicity of Boscalid to Birds and Mammals

Study Type [a]	Species [a]	Toxicity [a]	Daily Dose [b]
Birds			
Acute oral	Bobwhite	LD50 > 2000 mg a.i./kg bw	No conversion required
Dietary	Bobwhite	LC50 >5000 mg a.i./kg dw	LD50 > 1094 mg a.i./kg bw/d
		NOEC 5000 mg a.i./kg dw	NOEL 1094 mg a.i./kg bw/d
	Mallard	LC50 >5000 mg a.i./kg dw	LD50 > 1414 mg a.i./kg bw/d
		NOEC 625 mg a.i./kg dw (reduction in feed consumption)	NOEL 177 mg a.i./kg bw/d
Reproduction	Bobwhite	NOEC 300 mg a.i./kg dw (reduction in most reproductive parameters at highest test concentration)	NOEL 22 mg a.i./kg bw/d
		LOEC 1000 mg a.i./kg dw	LOEL 73 mg a.i./kg bw/d
	Mallard	NOEC 1000 mg a.i./kg dw (no effects)	NOEL 118 mg a.i./kg bw/d
		LOEC >1000 mg a.i./kg dw	LOEL > 118 mg a.i./kg bw/d
Mammals			
Acute oral	Rat	LD50 > 5000 mg/kg bw	No conversion required

Study Type [a]	Species [a]	Toxicity [a]	Daily Dose [b]
Reproduction (2 generation)	Rat	**Parental Toxicity:** [c] NOAEL: 1,000 mg a.i./kg diet for males (101.2 mg/kg bw/d); 10,000 mg a.i./kg diet for females (1062 mg/kg bw/d). LOAEL: 10,000 mg a.i./kg diet for males (1,035 mg/kg bw/d); Not determined for females. **Offspring Toxicity:** [c] NOAEL: 1,000 mg a.i./kg diet (101.2/106.8 mg/kg bw/d M/F). LOAEL: 10,000 mg a.i./kg diet (1035/1,062 mg/kg bw/d M/F) **Reproductive Toxicity:** [c] NOAEL: 10,000 mg a.i./kg diet (1,035/1,062 mg/kg bw/d for M/F). LOAEL: not determined	No conversion required

[a] From REG2004-02.
[b] Avian endpoints reported as a concentration were converted to a daily dose: Toxicity Dose = Concentration x (FIR/BW), where FIR and BW were drawn from original studies. Mammal endpoints were reported as doses in previous boscalid review. No conversion required for acute oral endpoints due to the nature of the test (already a dose).
[c] Effects included lower body weight and body weight gain in parental generation (males) and in offspring (males and females). No reproductive effects were observed.

Table 10 Screening Level Risk Assessment on Birds and Mammals

Generic body weight of organism (kg)	Exposure (# seeds/d) [a]	Toxicity (# seeds/d) [b]	RQ [c]
Birds			
0.02	1692	**Acute**: > 2500	< 0.7
		Dietary: > 1368	< 1.2
		Reproduction: 275	6.2
0.1	6627	**Acute**: > 12500	< 0.5
		Dietary: > 6838	< 0.97
		Reproduction: 1375	4.8
1	19347	**Acute**: > 125000	< 0.2
		Dietary: > 68375	< 0.3
		Reproduction: 13750	1.4

Generic body weight of organism (kg)	Exposure (# seeds/d) [a]	Toxicity (# seeds/d) [b]	RQ [c]
Mammals			
0.015	726	**Acute**: > 4688	< 0.2
		Reproduction: 949	0.8
0.035	1455	**Acute**: > 10938	< 0.1
		Reproduction: 2214	0.7
1	22877	**Acute**: > 312500	<0.1
		Reproduction: 63250	0.4

[a] Estimated exposure calculated as # seeds/g x FIR, where FIR is the food ingestion rate calculated using the following equations:

For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used:
FIR (g dry weight/day) = $0.398(BW \text{ in g})^{0.850}$

For generic birds with body weight greater than 200 g, the "all birds" equation was used:
FIR (g dry weight/day) = $0.648(BW \text{ in g})^{0.651}$

For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(BW \text{ in g})^{0.822}$

[b] Number of seeds to reach endpoint calculated as Daily dose (mg a.i./kg bw or mg a.i./kg bw/day) x generic body weight of organism (kg) ÷ Amount of active ingredient per seed (mg a.i./seed), where the amount of a.i. per seed = seed treatment rate (g a.i./kg seed) / # seeds/kg and was calculated to be 0.0016 mg boscalid per seed.

[c] Risk quotient (RQ) = exposure/toxicity. Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)

Table 11 Further Characterization of the Reproductive Risk Based on the LOEL

Generic body weight of organism (kg)	Exposure (# seeds/d) [a]	Toxicity (# seeds/d) [b]	RQ [c]
Birds			
0.02	1692	**Reproduction:** 913	1.9
0.1	6627	**Reproduction:** 4563	1.5
1	19347	**Reproduction:** 45625	0.4

[a] Estimated exposure calculated as # seeds/g x FIR, where FIR is the food ingestion rate calculated using the following equations:

For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used:
FIR (g dry weight/day) = $0.398(BW \text{ in g})^{0.850}$

For generic birds with body weight greater than 200 g, the "all birds" equation was used:
FIR (g dry weight/day) = $0.648(BW \text{ in g})^{0.651}$

For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(BW \text{ in g})^{0.822}$

[b] Calculated as the daily dose (NOEL = 68 mg a.i./kg bw/d) * generic weight of organism (kg) ÷ amount of active ingredient per seed (0.0016 mg a.i./seed).

[c] Risk quotient (RQ) = exposure/toxicity

Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)

Table 12 Alternative Fungicide Seed Treatments Registered on Canola and Oilseed Mustard

Crop(s)	Disease(s)	Active Ingredient	Classification
Canola	Seed rot and/or seedling diseases caused by *Rhizoctonia solani*	Azoxystrobin	11
		Carbathiin + thiram (export only)	7 + M
	Seed rot and/or seedling diseases caused by *Rhizoctonia solani* and *Fusarium* spp.	*Bacillus subtilis*	F6
Oilseed Mustard	Seed rot and/or seedling diseases (specific pathogens not identified)	Thiram	M
Canola and Oilseed Mustard	Seed rot and/or seedling diseases caused by *Rhizoctonia solani*	Iprodione + thiram	2 + M
		Trifloxystrobin	11
	Seed rot and/or seedling diseases caused by *Rhizoctonia solani* and *Fusarium* spp.	Fludioxonil	12
		Difenoconazole + metalaxyl + fludioxonil	3 + 4 + 12

Table 13 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed Use	Supported Use
To **control** seed rot caused by ***Rhizoctonia*** on canola **(including but not limited to *Brassica juncea, B. napus, B. rapa*)**, apply BAS 516 F ST to seed at a rate of 100 - 200 ml/100 kg seed. For use at commercial treatment facilities.	To **suppress** seed rot caused by ***Rhizoctonia solani*** on canola **and canola-quality *Brassica juncea***, apply BAS 516 F ST to seed at a rate of 100 - 200 ml/100 kg seed. For use at commercial treatment facilities.
To control seed rot caused by ***Fusarium*** on canola **(including but not limited to *Brassica juncea, B. napus, B. rapa*)**, apply BAS 516 F ST to seed at a rate of 100 - 200 ml/100 kg seed. For use at commercial treatment facilities.	To control seed rot caused by ***Fusarium* spp.** on canola **and canola-quality *Brassica juncea***, apply BAS 516 F ST to seed at a rate of 100 - 200 ml/100 kg seed. For use at commercial treatment facilities.

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